SC Breast & Cervical Cancer Early Detection Program (Best Chance Network)

PAP TEST SCREENING PROTOCOL

The following clinical elements serve as practice guidelines and Centers for Disease Control and Prevention's (CDC) minimum reporting requirements:

Screening

Cervical History includes:

- High risk factors for cervical cancer and CIN:
  - HIV infection/compromised immune system
  - Never or rarely screened by Pap testing
  - Prior history of cervical cancer or CIN
  - DES exposure in utereo
- Relative risk factors:
  - Cigarette smoking
  - Multiple sex partners
  - Early onset of sexual activity
- Hysterectomy – BCN will not fund Pap testing for women who had a hysterectomy for benign (non-cervical neoplasia) conditions.
  - Annual Pap tests will still be funded if hysterectomies were performed for cervical neoplasia (CIN II, III or cervical cancer).
  - Pap tests will be funded until 3 consecutive, BCN-funded annual Pap tests are performed with results of normal/negative if the reason for the hysterectomy is unknown.
  - If the hysterectomy was sub-total and the cervix is intact, continue screening the cervix per Pap test protocol.

Pap test screening is performed on all program eligible women who have an intact cervix or after total hysterectomy due to CIN 2, CIN 3 or cervical cancer:

- Pap frequency: BCN will only reimburse for a Pap test every third year after 3 or more consecutive, BCN- funded, annual Pap tests performed at 10-18 month intervals with normal/negative results are documented at DHEC. **Example: If negative Pap results were reported in 2002, 2003 and 2004, the next BCN funded Pap would be in 2007.**
- Pap test collection:
  - Sample the ectocervix with a non-wood spatula rotating 360 degrees at least once.
  - Sample the endocervix using a cytobrush and 180 degree rotation to avoid excess bleeding.
  - If the cervix is absent, sample the vaginal cuff using a spatula or tongue blade.
  - Prepare the specimen(s) according to laboratory specifications for conventional or liquid-based Pap tests.
- Conduct a bi-manual pelvic examination after the Pap test is collected.

Findings are reported using the 2001 Bethesda System Guidelines[1]:

- Adequacy of Specimen:
  - Satisfactory for evaluation
  - Unsatisfactory for evaluation
- Negative for Intraepithelial Lesion or Malignancy
- Atypical Squamous Cells – Undetermined Significance (ASC-US) – HPV DNA testing recommended using liquid based cytology or co-collection method (Hybrid Capture II Digene High Risk Panel)
- Atypical Squamous Cells – Cannot exclude High Grade SIL (ASC-H)

- Low Grade Squamous Intraepithelial lesion encompassing: HPV, Mild Dysplasia/CIN 1

- **High Grade Squamous Intraepithelial Lesion** (HSIL) encompassing: moderate and severe dysplasia, CIS/CIN 2 and CIN3.
- Squamous Cell Carcinoma
- Abnormal Glandular Cells including:
  - **Atypical Glandular Cells of Undetermined Significance (AGUS)**
  - **Endocervical Adenocarcinoma**
  - **Endocervical Adenocarcinoma in Situ**

Case management

Initiate BCN case management referral for all patients with abnormal cervical findings who require referral for a cervical diagnostic workup* – see attached guidelines. Initiate the referral by calling the DHEC Care Line number, 1-800-868-0404.

- Provide the intake staff the patient demographic and clinical information requested - the information will be forwarded to case managers who are medical social workers employed at the DHEC county health departments.

Case management referral **is not needed for ASC-US without a **positive high risk HPV test.***

Diagnostic

See attached Protocol for Follow-up of Abnormal Pap Tests[2]

Staging

Appropriate primary tumor, regional lymph nodes and distant metastasis (TNM) staging for cancer must be reported by the treatment facility.

Stage 1 or greater must be evaluated by gynecologic or radiation cancer specialists.

Treatment

Pathology reports of CIN 2 or 3 or invasive cancer require treatment be initiated within sixty (60) days from the date of diagnosis.

Women screened through BCN and diagnosed by biopsy with the cervical conditions of CIN 2, CIN 3 or invasive cervical cancer are eligible to apply for Medicaid coverage of treatment services through the SC Breast and Cervical Cancer Program. BCN follow-up providers assist patients with the application.

Resources:

1. NCI Bethesda System 2001: http://bethesda2001.cancer.gov/terminology.html

2. *2001Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities* in JAMA. 2002:287:2120-2129 for specific clinical management recommendations. Algorithms are available at www.asccp.org or 800-787-7227.

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SC BREAST & CERVICAL CANCER EARLY DETECTION PROGRAM/BEST CHANCE NETWORK
PROTOCOL FOR REPEAT PAPS AND FOLLOW-UP OF ABNORMAL PAP TESTS

Pap Test Results Using the Bethesda System 2001 Guidelines	Repeat Pap Test	Colposcopy/Colposcopy Directed Biopsy/ECC*	Date of Final Diagnosis
Negative for Intraepithelial Lesion or Malignancy	Annually, after three (3) consecutive BCN-funded annual Pap tests at 10-18 month intervals with negative results, then perform every third year, or annually if hysterectomy was performed for CIS/CIN 2 & 3 or cervical cancer		
Pap Specimen Unsatisfactory for Evaluation, Includes Obscuring Inflammation	Repeat in 2 to 4 months		
Atypical Squamous Cells – Undetermined Significance (ASC-US) – *HPV DNA testing (high risk profile) is preferred and covered by BCN*	1) High risk HPV DNA testing if liquid-based or co-collection method available 2) 4-6 months if slide-based Pap test 3) In 12 months if high risk HPV DNA test is negative	Should be performed if high risk HPV DNA test is positive or If 4-6 month repeat Pap test is done following a slide-based Pap test and results are ASC-US or above	Within 60 days of positive high risk HPV DNA test
Special Circumstances for ASC-US: Post-menopausal with evidence of atrophy & no contraindication to estrogen therapy	Acceptable Option: 1 week after completing 30 days of intravaginal estrogen therapy	Acceptable Option: Immediate or HPV DNA testing	Within 60 days of positive HPV DNA test
Atypical Squamous Cells – Cannot exclude High Grade SIL (ASC-H)		Refer immediately (or) perform procedure within 2 months	Within 60 days of abnormal Pap test
Low Grade Squamous Intraepithelial Lesion (LSIL) encompassing: HPV, Mild Dysplasia/CIN 1		Refer immediately (or) perform within 2 months	Within 60 days of abnormal Pap test
Special Circumstances for LSIL: Post-menopausal with evidence of atrophy & no contraindication to estrogen therapy	Acceptable Option: 1 week after completing 30 days of intravaginal estrogen therapy. If repeat Pap test is negative, repeat in 4-6 months	If ASC or greater, see above processes	If ASC or greater, within 60 days of last abnormal Pap test or positive high risk HPV DNA test
High Grade Squamous Intraepithelial Lesion (HSIL) encompassing: moderate and severe dysplasia, CIS/CIN 2 & CIN 3		Refer immediately (or) perform within 2 months	Within 60 days of abnormal Pap test
Squamous Cell Carcinoma		Refer immediately (or) perform within 1 month	Within 60 days of abnormal Pap test
Abnormal Glandular Cells including: Atypical Glandular Cells of Undetermined Significance (AGUS); Endocervical Adenocarcinoma; Endocervical Adenocarcinoma in Situ (AIS)		Refer immediately (or) within 1 month (with endocervical sampling)	Within 60 days of abnormal Pap test

**** Refer to BCN cervical follow-up providers to ensure that the diagnostic workup will be funded by the program. If results of the cervical biopsy are CIN 2 (moderate dysplasia), CIN 3 (severe dysplasia, CIS), or invasive cancer, treatment is required. The cervical follow-up providers should assist the patients with completion of a Medicaid application to cover treatment costs.***

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